



Docket No. 220002016004

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Tiffany B. Montgomery
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Walter L. MILLER et al.

Serial No.: 08/487,312

Filing Date: June 7, 1995

For: BOVINE GROWTH HORMONE

Examiner: C. Saoud

Group Art Unit: 1812

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COMMUNICATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This response to a Communication from the Office mailed 8 December 1997. No date for response was set.

The Communication indicates that the refusal of the Office to enter the Reply Brief filed 15 October 1997 was reconsidered, but that entry would still be refused because an argument that was assertedly not raised for the first time in the Examiner's Answer was included in the Reply.

Appellants respectfully request the Examiner to think about this again. There is no dispute on the facts. The issue of FDA approval was addressed in Appellants' Brief for the first time and the first time the Office addressed it was in reply. In Appellants' view, this amounts to the Office raising the issue for the first time in the Examiner's Answer. Otherwise, the usual practice of providing an opportunity for rebuttal of a newly articulated position would be subverted.

Perhaps an analogy to prosecution in general would be helpful. In filing an application, the applicant in effect, raises the issue of patentability of claims for the first time. By filing the application, the applicant asserts that the claimed subject matter is new, useful and unobvious over the prior art. The arguments "raised" by the Examiner in response are answers to this initial assertion. Similarly, here, the Office has "raised" its own position in response to an assertion by the Appellants which had not previously been made. This is, then, the first time that the issue was addressed or "raised" by the Office. Appellants should have the opportunity to reply.

In addition, Appellants would like to call the attention of the Examiner and the Board to a publication which occurred in the time intervening between the filing of the proposed Reply Brief and the presently filed paper. It will be noted that the possibility of infection derived from beef products was the cover story in the February 9, 1998 issue of *C&E News*, and begins on page 22. This and the publications previously submitted underline the importance of the distinction that Appellants have drawn between their claimed recombinantly produced bovine growth hormone and the prior art bovine growth hormone isolated from bovine pituitaries. The extremely repulsive photograph of dead cows on page 22 of the attached relevant article should be ample proof of how seriously this problem is taken and how important the distinction is.

Reconsideration and entry of both this paper and the paper filed 15 October 1997 is respectfully requested.

As this case raises an issue that apparently has not previously been addressed by the Office, an accelerated schedule toward Oral Hearing is respectfully requested.

Respectfully submitted,

Dated: March 5, 1998

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